EXHIBIT 171

From: Feniger, Angela
Sent: Wednesday, July 15, 2015 4:21 PM
To: Barbarite, Joseph; Wheeler, Douglas; Karaban, Dino; Poshni, Faiza; Shukla, Jaydeep
Subject: Buzzeo PDMA - DEA Audit Report April 28 - 30th, 2015
Attachments: Par Pharm Review June 2015.pdf; 1RR Reconciliation.pdf; 100B Reconciliation.pdf; Par Pharm SOPs June 2015.pdf

Dear All:

Attached is the DEA Audit Report that was conduct on April 28th – 30th 2015 by Buzzeo PDMA for your review.

I plan on scheduling an internal compliance team meeting the last week of July to review the report first amongst ourselves prior to the distribution to other departments. I would like to prioritize at this meeting which Buzzeo recommendation we plan on implementing and have a strategy in place to present to the impacted departments. Please let me know if you have an questions or comments. Regards,

Angela Feniger, MBA | Director, DEA Compliance & QA Documentation
Par Pharmaceutical Companies, Inc. | 2 Ram Ridge Road | Spring Valley, NY 10977
Phone: [redacted] | angela.feniger@parpharm.com
www.parpharm.com

From: bwilliamson@us.imshealth.com [mailto:bwilliamson@us.imshealth.com]
Sent: Thursday, June 04, 2015 9:19 AM
To: Barbarite, Joseph
Cc: Feniger, Angela; Sandra.Williams@us.imshealth.com
Subject: Reports from Site Review

Good Morning Mr. Barbarite

Please find attached reports from our onsite review conducted in April of this year.

As noted by the titles, one report has been prepared for the facility review and a second report has been prepared for the review of the SOPs. The "Reconciliation Documents" are attachments to the report for the facility review.

Sandra and I enjoyed meeting you and working with your staff.

Please let me know if you have questions and/or if we can help with any other DEA type issues.

Bob

Robert C. Williamson, Manager DEA Consulting
bwilliamson@us.imshealth.com
p. 770.565.4321 c.678.447.1724

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Via Mail and Email: Joseph.Barbarite@parpharm.com

June 4, 2015

Joseph Barbarite,
Vice President, Quality Assurance and Compliance
Par Pharmaceutical
One Ram Ridge Road
Spring Valley, New York 10977

Dear Mr. Barbarite:

Please find enclosed a report regarding the results of an onsite controlled substance regulatory review of the Par Pharmaceutical manufacturing facility in Spring Valley, New York conducted on April 28 through 30, 2015, by BuzzeoPDMA Consultants Robert (Bob) Williamson and Sandra Williams. As requested, Consultants provided follow up information from a previous review conducted in 2010 and also focused on controlled substance issues relating to the company's Drug Enforcement Administration (DEA) Manufacturer registrations. Also discussed while on site were issues and questions concerning the requirements of a "designated observer" to be present during manufacturing operations and the requirement for a "suspicious order monitoring system".

Controlled substance areas examined during the review included recordkeeping, reporting, security, quotas, ARCOS, inventory and batch records. A DEA type "accountability" was also conducted. Several Standard Operating Procedures (SOPs) were also reviewed. These will be forwarded to you via a separate letter.

As requested by Par Pharmaceutical staff, the review focused on the firm's DEA manufacturing registrations, including manufacturing procedures.

Findings and recommendations in this report are offered as consistent with DEA regulations and industry best practices for enhanced regulatory compliance for those areas reviewed. Par Pharmaceutical personnel were uniformly cooperative and engaged in efforts to establish needed processes and procedures consistent with regulatory requirements.

Please let me know if I can assist with any issues and/or items that require clarification. Also please also feel free to contact Bob Williamson, Senior Manager, DEA Consulting.

Sincerely,

Ronald W Buzzeo
Ronald W. Buzzeo, R.Ph.
Chief Regulatory Officer

Phar Pharmaceutical, Inc.

Spring Valley, New York 10977[1]

Background and Executive Summary

From April 28 through April, 30, 2015, Robert C. Williamson, Manager, DEA Consulting, and Sandra M. Williams, Senior Regulatory Consultant, both of BuzzeoPDMA, LLC (now part of IMS Health) conducted a controlled substance regulatory review at Par Pharmaceutical, Inc. (Par Pharma) in Spring Valley, New York. Angela Feniger, Director, DEA Compliance and QA Documentation, was the primary point of contact for the review at Par Pharma. Staff members Faiza Poshni, Manager, Controlled Substance QA Compliance and Jaydeep Shukla, DEA Compliance Specialist, Technical Writing and Documentation also provided ongoing assistance throughout the review.

Par Pharma manufactures approximately 24 controlled substances and maintains multiple Drug Enforcement Administration (DEA) registrations at multiple locations. Director Feniger requested that the BuzzeoPDMA Consultants focus on Par Pharma's two manufacturing registrations. These are located at [redacted]. Registration information for the two sites is displayed in the following tables.

Address	DEA #	Schedules	Exp. Date
[redacted]		I,II,IIN, III, IIIN,IV,V, LI	3.31.2016
		I, II, IIN,III, IIIN,IV, LI	3.31.2016

State of New York	State Agency	Description	Exp. Date
[redacted]		Class I Manufacturer Schedule I, II, III, IV, V	2.13.2016
		Class I Manufacturer Schedule I, II, III, IV	7.9.2015
		Manufacturer of Drugs and/or Devices	10.31.2015
		Manufacturer of Drugs and/or Devices	7.31.2017

The facility at [redacted] is the main manufacturing facility. Commercial product is manufactured at [redacted] and

[1] The town name has changed to Chestnut Ridge. The firm is gradually transitioning to the new address as it submits controlled substance renewal applications.

shipped to Par Pharma's Distribution Facility in [redacted] However, product development is conducted at [redacted] is registered with the DEA as a manufacturer since it meets the definition of a manufacturer as noted in Title 21, Code of Federal Regulations, Section 1300.01(b). [redacted]

BuzzeoPDMA conducted a site review in 2010. Most of the issues noted during the 2010 review were corrected; however, some are still open. BuzzeoPDMA Consultants noted that there were still issues related to the use of a central recordkeeping location for the storage of executed Forms 222. Also, issues were identified with respect to the requirement for a designated observer to be present during all manufacturing procedures. The issue was open and of ongoing interest at the firm. Additional follow up information is included in the report.

BuzzeoPDMA Consultants also reviewed a selection of Standard Operating Procedures as requested by the client. This information is summarized in a separate report.

The DEA conducted a scheduled regulatory inspection in 2012. According to staff, DEA Diversion Investigators appeared to be in a training mode and returned multiple times in an effort to work through the complicated manufacturing procedures. Eventually the supervisor accompanied them. Par Pharma staff conducted a major part of the review for the DEA. No adverse consequences were noted. BuzzeoPDMA Consultants conducted a similar DEA type accountability with the assistance of Par Pharma staff. Both bulk and finished product were audited. DEA type accountability charts are attached to the report. Variations were noted.

Consultants provided Par Pharma staff with an out briefing on the afternoon of the April 30th. Approximately 15 individuals attended the verbal briefing, including Joseph Barbarite, Vice President, Quality Assurance and Compliance and Konstantin Karaban, Senior Director, Compliance R&D and Quality.

[2] On August 25, 2014, Par Pharma requested that the DEA grant the multiple facilities a "campus registration." The local office of the DEA requested information which was furnished in February of 2015. No response had been received.

Summary of Findings

Primary areas identified for action/consideration are included below. A more detailed explanation follows in the body of this report.

- DEA required inventories and executed DEA Forms 222 may not be stored at a central location.
- Records of Schedule II controlled substance activity must be maintained separately from Schedule III-V records. Schedule II items should be placed in separate folders and listed separately on official records.
- Power of Attorney forms issued to execute Forms 222 must be maintained in the files with the executed Forms 222.
- Receiving documents must have the complete name, address and registration number of the person supplying controlled substance product.
- When recording dates of receipt and/or distribution, all DEA records, including shipments to reverse distributor must show the actual date of receipt or distribution.
- Observers for manufacturing processes and storage access must be designated in writing.
- A suspicious order monitoring system must be devised for all "non-practitioners" which includes manufacturers.
- There is inadequate capacity for Schedule II controlled substance storage in [redacted] Product accountability and CCTV camera coverage appear to be diminished and possibly compromised.
- Random drug testing of all employees is recommended or, at a minimum, for those who routinely handle controlled substances.
- The research activities performed as coincidental manufacturing are captured in laboratory notebooks in lieu of batch records. The experimental activities documented do not contain sufficient information to satisfy the DEA manufacturing documentation requirements.
- Trend analysis of controlled substance losses/variances should be conducted to ascertain acceptable deviations and help establish what constitutes a "significant" and reportable controlled substance loss. The current [redacted] observed is not appropriate for most conditions.

- It is recommended that an SOP be written to describe the ARCOS data capture, report development and EDI submission process. Required year end manufacturing codes are not being reported.

- The current batch reconciliation to base API used is performed at several defined process stages by calculating the theoretical % of API. The process is time consuming and will impose a time burden as additional CII drugs are manufactured.

- A review of manufacturing batch records, and the most recent biennial and year end inventories revealed that recovered manufacturing waste, process tailings and out of specification controlled substance materials are grouped together as "in-process" instead of identified individually.

The following report details regulatory issues, as well as recommendations to enhance compliance. Also noted are comments and recommendations that should be considered to minimize risk and provide a best practices environment.

Assessment Report

This assessment primarily focuses on issues relating to Par Pharma's controlled substance registrations as a Manufacturer at [redacted] A DEA type "accountability" was also performed for each registration. The "accountability" was performed on both raw material and finished product. The "accountability" was performed with the assistance of Par Pharma staff that identified required records and tabulated relevant entries. The purpose of the "accountability" process was to provide staff with information, background and training on DEA procedures which would be helpful during a DEA site review. A selection of Par Pharma Standard Operating Procedures was also reviewed as requested by the firm. Information pertaining to the review of the Standard Operating Procedures is contained in a separate report.

Matters relating to DEA inventory, recordkeeping, reporting, security, quotas, ARCOS and employee hiring practices were reviewed. Findings or recommendations noted concerning controlled substance manufacturing have also been included. Recommendations are offered as consistent with DEA requirements and industry best practices.

Issues identified are listed below and include regulatory citations where applicable as well as recommended responses and best practices.

Central Recordkeeping

- Records for all controlled substance locations are maintained by DEA Compliance Specialist Shukla. According to Director Finegar Par Pharma has furnished the DEA with a request to maintain records at a central location as

required by 21 CFR 1304.04 (a) (1) and (b)(1). DEA central recordkeeping regulations do not include all records. In the regulations, "financial and shipping" records are specifically mentioned. It was noted during the review that **executed Forms 222** were maintained at the central location, and the regulations specifically cull this out as not being an approved activity. The same issue was noted for the **official DEA inventories** which must be maintained at the registered location.

Requirements

21 CFR §1304.04 Maintenance of records and inventories

(a) ...

(1) Financial and shipping records (such as invoices and packing slips but not executed order forms subject to §§1305.17 and 1305.27 of this chapter) may be kept at a central *location*...

(b) All registrants that are authorized to maintain a central recordkeeping system under paragraph (a) of this section shall be subject to the following conditions:

(1) The records to be maintained at the central record location **shall not include executed order forms and inventories**, which shall be maintained at each registered location.

Review/Findings / Recommendations

Since the regulations are clear, Par Pharma is e required to maintain the DEA required inventories and executed DEA Forms 222 at the required registered location.

As a practical matter, this will require coordination with each site to identify responsible individuals and locate a suitable repository for the records. **Copies** of records may still be kept at [redacted], along with other permissible DEA documents.
If the DEA approves Par Pharma's request to have a campus registration, the number of registrations will be reduced and the need to maintain records at a central location may be eliminated. This may also present an optimum solution.

Powers of Attorney to Sign Forms 222

- As noted above, Compliance Specialist Shukla maintains all the required records for multiple registrations. He is also involved in ordering controlled substances including Schedule II controlled substances. Consultants noted that he is authorized to sign Forms 222 through a DEA compliant "Power of Attorney" issued by a corporate officer. However, Consultants learned that the Power of

Attorney to sign Forms 222 is not filed with the executed order forms as required by the regulations.

Requirements

21 CFR § 1305.05 (a) (b) Power of Attorney

(a) A registrant may authorize one or more individuals, whether or not located at his or her registered location to issue orders for Schedule I and II controlled *substances....by executing a power of attorney for each such individual, if the* power of attorney is **retained in the files, with executed Forms 222**... *for the* same period as any order bearing the signature of the attorney.

Review/Findings/Recommendations

According to staff, the Power(s) of Attorney are filed in Controlled Substance Manager Poshni's office. The originals could be copied and maintained with the Forms 222 as required by the regulations and a copy could be maintained in the current office location.

Consultants also noted that a logbook has been prepared to account for Forms 222 which have been received and then used. This is a "best practice" and not required by the regulations, but should continue. Consultants recommended that the logbook be revised to show the serial numbers of the Forms 222, which would provide for better accounting.

DEA Recordkeeping Requirements

- Required records relating to the inventory, receipt, distribution, use, or other disposition of Schedule II controlled substances must be maintained separately from Schedule III – V substances. In addition, controlled substance records of Schedule III – V substances must be kept either separately or in a readily retrievable form.

- In addition to filing conventions, DEA regulations contain specifications regarding the format for official records and required information to be included on each required record. The maintenance of records is a fundamental part of the "closed system of distribution" which is the regulatory framework for the Controlled Substances Act of 1970 and all subsequent amendments and regulations. In essence, the "closed system of distribution" seeks to assure that only authorized individuals (registrants) may purchase and/or ship (distribute) controlled substances. Required records must contain enough information for officials to assure that registrants are only transferring controlled substances to authorized individuals.

- Consultants noted that Par Pharma's system of record maintenance was generally designed to observe the rules and requirements as contained in the Code of Federal Regulations. Compliance issues were noted in specific limited areas.

- Schedule III through V receipts for registration are maintained in a separate binder which is further subdivided into separate plastic receiving folders. Each receiving event contains inventory receiving information, bills of lading, inspection reports, etc – including dates of receipt. However, it was noted that receiving documentation from Anchen and Jubilant did not have the **DEA registration number of suppliers**. (This was noted on the documents for the [redacted] Registration.)

- Destruction records are also maintained in a separate binder and each destruction event is documented in a separate plastic sleeve. Chesapeake Waste Solutions is the reverse distributor used by Par Pharma. Each destruction event noted in the [redacted] destruction folder contains an "inventory of destruction" which includes the name, address and registration number of both Par Pharma and Chesapeake Waste; however, the **actual date of shipment** is missing from the documents. It was also noted that Schedule II items are commingled with Schedule III through V items on the destruction records.

Requirements

21 CFR §1304.21 General requirements for continuing records

(a) *Every registrant required to keep records ... shall maintain on a current basis* a complete and accurate record of each substance manufactured, imported, *received, sold, delivered, exported, or otherwise disposed of by him/her...*"

21 CFR §1304.22 (a) Records for manufacturers, distributors, dispensers, researchers, importers, exporters, registrants that reverse distribute, and collectors.

"Each person registered ... to manufacture... controlled substances shall maintain records with the information listed below.

(a) Records for manufacturers.

(1) *For each controlled substance in bulk form ...*

(2) For each controlled substance in finished form,

(i) The name of the substance;

(ii) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(iii) The number of containers of each such commercial finished form *manufactured from bulk form by the registrant ...*

(iv) The number of units of finished forms and/or commercial containers acquired from other persons, **including the date of and number of units and/or commercial containers in each acquisition to inventory and the name, address, and registration number of the person from whom the units were acquired**;

(v) The number of units of finished forms and/or commercial containers imported ...

(vi) The number of units and/or commercial containers manufactured by the *registrant from units in finished form received from others or imported ...*

(vii) The number of commercial containers distributed to other persons, including the date of and number of containers in each reduction from inventory, and **the name, address, and registration number of the person to whom the containers were distributed;**

(viii) The number of commercial containers exported ... and

(ix) The number of units of finished forms and/or commercial containers **distributed or disposed of in any other manner by the registrant** (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, **the name, address, and registration number of the person to whom distributed**, and the quantity in finished form distributed or disposed.

21 CFR §1304.21 (d) General requirements for continuing records.

"In recording dates or receipt, ... distribution... or other transfers, **the date on *which the controlled substances are actually received... distributed... or* otherwise transferred** *shall be used as the date of receipt or distribution..."*

21 CFR §§ 1304.04(f) (1) and (2) Maintenance of records and inventories.

(1) Inventories and records of controlled substances listed in **Schedules I and II shall be maintained separately** from all of the records of the registrant; and

(2) Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant

Review/Findings/Recommendations

Deficiencies noted can be corrected by training. Required information can be supplied by simple handwritten additions to required documents. Stamps are also frequently used to provide a place for employees to write out all the required information.

Consultants also discussed the practice of including both Schedule II controlled substances and Schedule III through V controlled substances on the same destruction document. It is recommended that this practice be avoided as the DEA may consider it to be a violation of the requirement to maintain separate files for Schedule II controlled substances.

Biennial & Year-end Inventory

- A biennial inventory is a complete and accurate record of all controlled substances on hand and/or in control of the registrant. General inventory requirements are described in 21 CFR § 1304.11(a). Inventories must include **all forms of controlled substances including: API; finished product; samples; waste product intended for disposal; and any other form in the possession of the registrant.**

- A year-end inventory is a physical inventory performed on the last day of the year, 12/31, and is described in 21 CFR § 1304.33(b). This inventory allows for ARCOS reporting and Year-End Reporting of the completed calendar year. The data collected is used for ARCOS, Quota submissions, and United Nations treaty obligations.

- Currently, controlled substance biennial inventories at Par Pharma are conducted twice a year, approximately every 6-months, [redacted] The most recent inventory provided for review, early December 2014, was reconciled to the year-end physical inventory performed on December 31, 2014. These inventories provided the starting point for the DEA-like accountability performed during the review.

Requirements

21 CFR § 1304.11 Inventory requirements

"(a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. . . A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e) (4) of this section. . . The inventory may be taken either as

of opening of business or as of the close of business on the inventory date and it shall *be indicated on the inventory."*

(c) Biennial inventory date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

"(e) Inventories of manufacturers, distributors, dispensers, researchers, importers, exporters and chemical analysts. Each person registered or authorized (by §1301.13 or §§1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export, conduct research or chemical analysis with controlled substances and required to keep records pursuant to §1304.03 shall include in the inventory the information listed below.

(1) Inventories of manufacturers. Each person registered or authorized to manufacture controlled substances shall include the following information in the inventory:

(i) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form, the inventory shall include:

(A) The name of the substance and

(B) The total quantity of the substance to the nearest metric unit weight consistent with unit size.

(ii) For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:

(A) The name of the substance;

(B) The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and

(C) The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number or volume thereof.

(iii)For each controlled substance in finished form the inventory shall include:

(A) The name of the substance;

(B) Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(C) The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and

(D) The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

(iv) **For each controlled substance not included in paragraphs (e)(1) (i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:**

(A) The name of the substance;

(B) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(C) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

21 CFR §1304.33 Reports to Automation of Reports and Consolidated Orders System (ARCOS)

(b) Frequency of reports. Acquisition/Distribution transaction reports shall be filed ...Inventories shall provide data on the stocks of each reported controlled substance on hand as of the close of business on December 31 of each year, indicating whether the substance is in storage or in process of manufacturing. These reports shall be filed not later than January 15 of the following year. Manufacturing transaction reports shall be filed annually for each calendar year not later than January 15 of the following year, except that a registrant may be given permission to file more frequently (but not more frequently than quarterly).

Review/Finding/Recommendations

The biennial inventory is commonly used by DEA as the starting point for an "accountability" audit during its inspections. Depending on the time of arrival, DEA may examine up to a full 12 months of records instead of no more than 6 months. A longer audit period increases the likelihood of error and consequent potential liability to the company. Also, record retention should be limited to the maximum length of time required by either federal or state regulations, whichever is longer and company policy and legal procedures / considerations. Though DEA requires a 2-year retention for most records, they may review older records if they are available. This opens the door to more errors and discrepancies. Limit your risks; discard records as soon as appropriate.

The YEI is required for ARCOS reporting and to complete the "Inventory" section of the Year-end report (YER). A YER is filed for each DEA Drug Code for which quota was issued and/or inventory was held at any time during the year. Items required on the year-end report and/or for ARCOS should be clearly identified in the inventory - recovered waste, non-recovered waste, materials pending disposal, QC samples returned, etc.

The 2014 YER and the 2014 ARCOS year-end report do not show the separation of **waste and non-salable material from other in-process materials**. It is impossible to identify the material held for destruction when it is grouped in with true in-process (intermediate step manufacturing materials). These separate controlled substance materials must be identified and reported as individual items, not pooled together. Reference 21 CFR§ 1304.11 (e) (1).

It should be noted that while the regulatory requirements for analytical laboratory inventories allow for less than 1 kilograms of any controlled substance, less than 20 grams of a Schedule I hallucinogen, and less than .5 grams of lysergic acid to be excluded from inventory, it is typically DEA's expectation that all product be inventoried and recommended by BuzzeoPDMA. In those instances where quantities are very small and weighing of contents impracticable, gross weights of the containers should be obtained.

ARCOS

- ARCOS is the DEA's Automation of Reports and Consolidated Orders System which requires certain registrants (including manufacturers) to submit required monthly or quarterly manufacturing and distribution activity reports. The Electronic Data Interchange (EDI) system permits electronic transmission of the reports directly to DEA. The ARCOS reporting requirements can be found at 21 CFR §1304.33 and step by step instructions are provided in the on-line ARCOS Registrant Handbook on the DEA Diversion Control website.

- The 2014 year-end ARCOS [redacted] Manufacturing report dated 12/31/2014 did not include several required year-end manufacturing codes: "W" for waste, "N" for non-recovered waste, "Q" for QC samples taken from inventory, "J" for QC samples returned to inventory, "U" for any controlled substance converted from one schedule into a finished dosage of another schedule. It was also explained that the year-end in-process code "4" was used as a "catch all" to document not only manufacturing in-process material, but process wastes and overages.

- (Par Pharma personnel stated that they had previously reported the Manufacturing codes, but had been instructed by ARCOS personnel that it was not necessary.)

Requirements

21 CFR §1304.33 Reports to Automation of Reports and Consolidated Orders System (ARCOS)

(b) Frequency of reports. Acquisition/Distribution transaction reports shall be filed every quarter not later than the 15th day of the month succeeding the quarter for which it is submitted; except that a registrant may be given permission to file more frequently (but not more frequently than monthly), depending on the number of transactions being reported each time by that registrant. **Inventories shall provide data on the stocks of each reported controlled substance on hand as of the close of business on December 31 of each year, indicating whether the substance is in storage or in process of manufacturing.** These reports shall be filed not later than January 15 of the following year. Manufacturing transaction reports shall be filed annually for each calendar year not later than January 15 of the following year, except that a registrant may be given permission to file more frequently (but not more frequently than quarterly).

(c) Persons reporting. For controlled substances in Schedules I, II, narcotic controlled substances in Schedule III, and gamma-hydroxybutyric acid drug product controlled substances in Schedule III, each person who is registered to manufacture in bulk or dosage form, or to package, repackage, label or relabel, and each person who is registered to distribute, including each person who is registered to reverse distribute, shall report acquisition/distribution transactions. In addition to reporting acquisition/distribution transactions, **each person who is registered to manufacture controlled substances in bulk or dosage form shall report manufacturing transactions** on controlled substances in Schedules I and II, each narcotic controlled substance listed in Schedules III, IV, and V, gamma-hydroxybutyric acid drug product controlled substances in Schedule III, and on each psychotropic controlled substance listed in Schedules III and IV as identified in paragraph (d) of this section.

> (d) Substances covered. (1) Manufacturing and acquisition/distribution transaction reports shall include data on each controlled substance listed in Schedules I and II, on each narcotic controlled substance listed in Schedule III (but not on any material, compound, mixture or preparation containing a quantity of a substance having a stimulant effect on the central nervous system, which material, compound, mixture or preparation is listed in Schedule III or on any narcotic controlled substance listed in Schedule V), and on gamma-hydroxybutyric acid drug products listed in Schedule III...
>
> (e) Transactions reported. Acquisition/distribution transaction reports shall provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies). **Manufacturing reports shall provide data on material manufactured, manufacture from other material, use in manufacturing other material and use in producing dosage forms.**

Review/Finding/Recommendations

Only Manufacturers and Distributors are required to submit ARCOS reports. Various codes are used to designate specific activities, such as "P" for purchases and "S" for sales. Some codes only require the full year totals to be reported at year end, such as "3" for year-end inventory and "4" for year-end in-process inventory. Other quarterly or year-end codes such as "W" for recovered waste and "N" for non-recovered waste are only required of Manufacturers to report.

Unless a written waiver has been provided by DEA, the regulation is clear and still present in the on-line ARCOS Registrant Handbook. Manufacturing codes W, N, Q, J and U are to be reported at least annually in the year-end ARCOS.

Waste material, scrap and other non-salable controlled substance manufacturing by-products are measured and calculated separately in the physical year-end inventory and batch records, they should be reported under the proper codes.

It is recommended that Par Pharma write an SOP describing the ARCOS reporting process, frequency, required codes and the individual or department responsible for reporting.

Research Laboratory Notebooks

- DEA allows for certain co-incident activities under a Manufacturing Registration. Research is one of those activities. As such, the documentation and records required under a manufacturing registration must also be observed for the research activities.

- DEA regulations require that controlled substance manufacturing be documented and the records contain information that would be required for a DEA type "accountability" investigation/audit.

- Research conducted under the manufacturing registration as a co-incident activity, such as pre-clinical research for substances listed in those schedules for which authorization as a manufacturer was issued, is documented in laboratory Notebooks instead of batch records. This process allows for a less structured, more relaxed flow of creativity and development ideas than approved, GMP batch records permit. Unfortunately, this documentation process may have the negative effect of excluding elements required by DEA Manufacturers. The same controlled substance documentation requirements observed for DEA Manufactures are required for co-incident activities performed under that registration.

Requirements

21 CFR §1301.13(e) Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities

(e).... Any person, when registered to engage in the activities described in each subparagraph in this paragraph, shall be authorized to engage in the coincident activities described without obtaining a registration to engage in such coincident activities, provided that, unless specifically exempted, he/she complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities...

21 CFR § 1304.22 (a) Records for manufacturers, distributors, dispensers, researchers, importers, exporters, registrants that reverse distribute, and collectors

"Each person registered or authorized ... to manufacture... controlled substances shall maintain records with the information listed below.

(c) Records for manufacturers...

(i) For each controlled substance in bulk form to be used in, or capable of use in, or being used in, the manufacture of the same or other controlled or noncontrolled substances in finished form,
(ii) The name of the substance
(iii) The quantity manufactured
(iv) ...
(v) The quantity used to manufacture the same substance in finished form including:

(A) The date and batch or other identifying number of each manufacture;
(B) The quantity used in the manufacture;
(C) The finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter); (D) the number of finished forms manufactured
(D) The number of units of finished form manufactured;
(E) The quantity used in quality control
(F) The quantity lost during manufacturing and the causes therefore, if known
(G) The total quantity of the substance contained in the finished form;
(H) The theoretical and actual yields: and
(I) Such other information as is necessary to account for all *controlled substances used in the manufacturing process...*"

(c) Records for dispensers and researchers. Each person registered or authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser. In addition to the requirements of this paragraph, practitioners dispensing gamma-hydroxybutyric acid under a prescription must also comply with Sec. 1304.26.

Review/Findings/Recommendations

R&D Manufacturing Researcher Notebook, RB-151, Adderall IR Tablets:
An experiment exploring stability of split tablets from 2-dosages of Adderall IR tablets (7.5 mg and 10 mg) was reviewed. This experimental activity was within the December 2014 - May 2015 time frame for the review period. Four split-tablet stability processes were documented on pages 123-126, but did not provide the required information to meet the records requirements of a DEA manufacturer.

Documentation deficiencies included: the lack of the initials weights of the controlled substance (Adderall IR tablets); the batch numbers of the newly created experimental sample bottles; a list of materials & equipment used for the experiments; the total quantity of controlled substance used was vaguely described as either 64-split tablets or 100 split tablets; any unused or damaged tablets returned as waste to be discarded; a description of the labels or label information placed on the stability bottles; there was no documented designated observer and no identification of the CII approved device in which the experimental bottles were to be stored.

BuzzeoPDMA recommends implementing the draft SOP-QA-0066, Inventory Control of Controlled Substances in the R&D Manufacturing Area and associated FRM-QA-0038, R&D Manufacturing Inventory Form. The SOP and form were developed to eliminate such documentation non-compliance issues and to assist in capturing the required accountability and/or reconciliation data necessary to complete DEA required reports (ARCOS, Biennial Inventory, Year-End Inventory).

Designated/Authorized Observers:

- A draft SOP, SOP-QA-0065, DEA Designated Observer was presented for review and will be discussed further in a separate report. However, while the topic of the Designated Observer and the associated responsibilities have been a point of discussion at Par Pharma, and in industry in general. DEA regulations are very specific in their requirements: this person/s must be identified in writing, they are responsible for defined "Limited Access" areas, and while permitted to engage in manufacturing activities, they must provide continuous surveillance to detect and detain unauthorized persons.

- The Designated Observer's main objective is to ensure the limited access areas where controlled substances are present remain free from unauthorized personnel. If a non-authorized individual is present for legitimate business reasons, repairs or maintenance, etc., the Designated or Authorized Observer is to monitor their presence. This is the extent of the requirement in the regulations, 21 CFR § 1301.73(b).

- The draft Designated Observer SOP extends the responsibilities substantially and may require a third person not associated with the manufacturing activity to be present to fulfill the roll. This is in excess of the DEA's intent, but as a best practice may be entirely appropriate for Par Pharma's business goals and security concerns.

Requirements

21 CFR § 1301.73(b) Physical security controls for non-practitioners; compounders for narcotic treatment programs; manufacturing and compounding areas

"(b) Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees **designated in writing** as responsible for the area. "Limited access" may be provided, in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as responsible for

the area may be engaged in the particular manufacturing operation being conducted: Provided that he is able to provide continuous surveillance of the area **in order that unauthorized persons may not enter or leave** the area without his knowledge."

21 CFR § 1301.72(d) Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

"(d) Accessibility to storage areas

The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing."

Review/Findings/Recommendations

Manufacturing observers should be designated in writing either as a posted list in the manufacturing area and as part of the manufacturing record itself. The observers may be engaged in the manufacturing process itself and need not be independent of the activity being performed. The list should be retrievable for the manufacturing activity.

A second list of individuals authorized to observe non-routine access to the controlled substance safes and storage areas should be created and posted at each location.

A process to review, train and confirm the accuracy of designated observer and access lists should also be developed and incorporated into an SOP.

It should also be noted that 21 CFR 1301.73(a) requires that in-process substances be returned to the controlled substance storage area at the termination of the process. Controlled substances engaged in a continuous process and can not be interrupted may remain in the manufacturing area or tanks, vessels, bins or bulk containers containing the controlled substances shall be securely locked, with adequate security for the area.

Suspicious Order Monitoring (SOM) – Due Diligence Program

- All manufacturers (**non-practitioners**) of controlled substances must design and operate a system that discloses suspicious orders of controlled substances and report those orders to DEA. Further, the company must make a good faith effort to ensure that it is shipping controlled substances to companies that are appropriately registered to receive those substances.

- Par Pharma has regulatory responsibility to report suspicious orders to the DEA for both their manufacturing registrations and their distribution registration, since these registrations are classified as "non-practitioners" in the law and regulations. As noted, all controlled substances manufactured at [redacted] are either distributed to [redacted] where there is no additional distribution or to the primary distribution center in [redacted]

- According to staff the major customers are large accounts, including the "Big Three" (McKesson, AmerisourceBergen and Cardinal) and other large chains. Although the number of customers may be relatively small, it was reported that there were 145 "ship to addresses" in one month. The DEA's expectation as noted in the regulations and additional communications to registrants is that the orders should be evaluated and reported to the DEA if suspicious as defined in the regulations.

- The person responsible for Par Pharma' Suspicious Order System was not available for interview; however, the firm provided an SOP entitled Suspicious Order Monitoring for review. According to the SOP Par Pharma's top trade customers are asked to submit "usage" reports. Purchase orders are evaluated against the usage reports and if the amounts are higher, the Buyer contacts the customer to inquire about the higher quantity. A written explanation is requested and reviewed by the Buyer. (Additional information regarding this SOP is contained in a separate report.)

- Customer registration information is verified in real time at the DEA's diversion control web site (deadiversion@usdoj.gov) when the customer is initially signed and then quarterly.

- The SOP does not contain instructions for reporting suspicious orders. Instead there is a section, which is "bolded" which states that "Criminal Activities" will be reported to federal and state agencies, including the Food and Drug Administration and the board of pharmacy, "within three days."

Requirements

21 USC § 802 (21)

(21) The term "practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.

21 CFR §1301.74: Other security controls for **non-practitioners**; narcotic treatment programs and compounders for narcotic treatment programs

(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. **Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.**

Review/Findings/Recommendations

Par's current SOM system as it currently operates may be difficult to explain and defend during a DEA review.

SOM programs should incorporate the following elements into the order fulfillment process. It is recommended that Par Pharma evaluate its ongoing program in light of the following recommendations and best practices with an aim to improve their SOM program.

- **A Defensible Statistical SOM Model that**
  - Identifies orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency
  - Statistically based model
- **Appropriate Due Diligence and "Know Your Customer" Activities**
  - Determine legitimacy of existing and potential new customers (customers and customer's customers)
- **Appropriate Review and/or Investigations of Pended Orders**
  - Differentiation of appropriate roles for "sales" and "regulatory."
- **Clear, Comprehensive SOMs SOPs**

- Procedures to identify investigative process, process to clear orders, DEA reporting, closing accounts, etc.

- **Management Support and Employee Training**
  - Development of a culture of compliance with the regulatory requirements and respect for the danger of controlled substance abuse.

Controlled Substance Security

- Proper security is essential to safeguard controlled substances and prevent diversion. Christopher Fraser, CPP, Associate Director, Security was interviewed on the morning of April 30th and then provided Consultant Williamson with a tour of [redacted]. Director Fineger was also present for the tours.

- [redacted]

- [redacted]

- [redacted]

- [redacted]

[redacted]

Requirements

21 CFR § 1301.71(a) Security requirements generally

"All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances."

Review/Findings/Recommendations

The following security best practices and recommendations were developed during the security review:

[redacted]

[redacted]

- BuzzeoPDMA also recommends that the names of the individuals who are allowed to be in the secure work areas be posted on the outside of the vault and cage.
- As a best practice, it is best to break down an incoming shipment to assure that it complete before signing for the shipment. It appeared from interviews with staff that they [redacted].

[redacted]

- Consultants also recommend that controlled substance alarms be tested quarterly. Alarm testing should be included as a security procedure and the results of the tests should be recorded.

[redacted]

Employee Screening and Responsibilities

- DEA regulations recommend that **non-practitioners** (e.g. manufacturers) conduct employee screening of individuals to minimize or prevent the incidence of

controlled substance diversion. Information regarding employee background investigations was initially obtained during interviews with Associate Security Director Christopher Fraser. On April 30, 2015, Consultants also interviewed Valerie Pusaver, Generalist, Human Resources, regarding the firm's hiring practices.

- Par Pharma conducts background investigations on all employees every five years. Background investigations for temporary employees are conducted through an agency agreement with the company who furnishes the temporary employees. Background investigations are also conducted at any time an employee is assigned a duty that will involve handling a controlled substance.

- The firm does pre-employment and "for cause" drug testing.

- Par Pharma has policies to prohibit illegal drug use which are contained in documents provided to employees at the time of hire. All illegal drug use is prohibited, even when not at work. There is a "Drug Free Work Place" program; however, the program is limited to the documents signed by employees at hire.

Requirements

21 CFR § 1301.90 Employee screening procedures

> "**It is the position of DEA that the obtaining of certain information by non-practitioners is vital to fairly assess the likelihood of an employee committing a drug security breach.** The need to know this information is a matter of business necessity, essential to overall controlled substances security. In this regard, it is believed that conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry. It is, therefore, assumed that the following questions will become a part of an employer's comprehensive employee screening program:
>
> Question. Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, location, date and sentence.
>
> Question. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details.
>
> Advice. An authorization, in writing, that allows inquiries to be made of courts and law enforcement agencies for possible pending

charges or convictions must be executed by a person who is allowed to work in an area where access to controlled substances clearly exists. A person must be advised that any false information or omission of information will jeopardize his or her position with respect to employment. The application for employment should inform a person that information furnished or recovered as a result of any inquiry will not necessarily preclude employment, but will be considered as part of an overall evaluation of the person's qualifications. The maintaining of fair employment practices, the protection of the person's right of privacy, and the assurance that the results of such inquiries will be treated by the employer in confidence will be explained to the employee."

21 CFR § 1301.91 Employee responsibility to report drug diversion

"... *It is* the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has **an obligation to report** such information to a responsible security *official of the employer... A failure to report information of drug* diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area. The employer shall inform all employees concerning this policy."

21 CFR § 1301.92 Illicit activities by employee

"It is the position of DEA that employees who possess, sell, use or *divert controlled substance will subject themselves to ...* prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment etc. in determining whether to suspend, transfer, terminate or take other action against the employee."

Review/Findings/Recommendations

Par Pharma's hiring documents/procedures are generally consistent with the language contained in the regulations quoted above. Par Pharma may consider reviewing 1301.91 and changing their documents to reflect the specific language noted in the regulation.

It is also recommended that Par Pharma require employees **to read and sign all of the firm's Drug Abuse Policies and Codes of Conduct on an annual basis**.

This will assure that employees have a proper understanding of what the firm's expectations are.

While not a DEA requirement, it is recommended that pre-employment, for cause, **and random urine screening** of all employees be conducted as a deterrent to illegal employee drug use.

Prescription drug abuse is increasing in prevalence among the general population and is considered by DEA as a part of an industry culture of compliance. Care should be exercised in selecting an appropriate drug panel for testing.

Trend Analysis

- DEA requires that any theft or "significant" loss of a controlled substance be reported to the agency in writing within one business day. Defining a "significant" loss varies with different "settings" or interpretations.

Requirements

21 CFR § 1301.74(c) Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs

"(c) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss. The supplier is responsible for reporting all in-transit losses of controlled substances by the common or contract carrier selected pursuant to paragraph (e) of this section, within one business day of discovery of such theft or loss. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the theft or loss. Thefts and significant losses must be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;

(2) The specific controlled substances lost;

(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;

(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,

(5) Whether the specific controlled substances are likely candidates for diversion;

(6) Local trends and other indicators of the diversion potential of the missing controlled substance."

Review/Findings/Recommendations

Variances encountered during any handling of a controlled substance should be determined based on actual measured deviation. Trend analysis should be conducted on material variations during any handling/manufacturing process.

Variances can then be determined based on actual and statistical data. An actual trended variance provides for a defensible point of reference and will assist in fulfilling reporting requirements to DEA if a significant loss is encountered.

SOP-QA-0052 version 2.0 (Receipt and Inventory Control of Controlled Substances, Sections IV, Procedure, A.7, D.7, and F.5) notes that a [redacted] variance or [redacted] weight discrepancy between the physical weight and the documented weight in any inventory will require investigation. This range is not appropriate to every circumstance. A [redacted] variance of kilogram quantities may be a very significant amount, while a [redacted] variance of a milligram quantity may be scale variation.

It is recommended that the criteria utilized in determining a significant loss threshold be documented within a Standard Operating Procedure (SOP) on a sliding scaled basis, supported by trended data. The average weight differences from a minimum of 10 like items (10 - multi kilogram bulk API drums; 10 - gram(s) Quality Control samples; 10- milligram(s) analytical reference sample; etc.) should be trended initially to establish a base alert/action range for variances. Once a baseline is created, the trends could be collected at some reoccurring frequency to determine the accuracy of the ranges.

Training

- According to Director Feniger, employees are trained on Standard Operating Procedures as required for each new job task.

Recommendations

Consultants identified numerous opportunities for a more robust training program. Training for individual standard operating procedures is a requirement and a

foundation for satisfactory job performance. However, additional training is recommended for employees who handle controlled substances. This recommendation is for a more complete orientation to DEA's rules and regulations. The thought behind this recommendation is that an overview of the concepts that drive the DEA's regulatory concepts will make all the individual procedures make more sense. Some of the topics that might be covered in such a training session are listed as follows:

- Overview of the Controlled Substances Act
- The DEA's "closed system of distribution"
  - Registration Requirements
  - Inventory Requirements
  - Recordkeeping Requirements
  - Reporting Requirements
  - Controlled Substance Security
- DEA's Scheduling Process
- Drug Quotas
- DEA Forms 222

Consultants also recommend corporate training for all employees regarding the company's policies and expectations regarding controlled substance use and company expectations. This would be presented by a senior official to communicate the drug free work place policy.

Both training sessions would provide an opportunity for managers to discuss the importance of corporate security, including the requirement to observe the use of card access readers in all places they have been installed.

Follow Up From 2010 Review (Still not in Compliance)

The following items were noted during the 2010 and remained open during the current review.

Finding No. 1 - Procedure for filling out DEA Form 222

An "internal" transfer of material from manufacturing to the analytical lab was preceded by a DEA form 222 being issued. The material, Fentanyl Sublingual Spray, RB154L024 was sent from [redacted] (Manufacturer) to [redacted] (Analytical). The order form was completed by Compliance Specialist Shukla, but the supplier's DEA Registration number was left blank. He explained that is was the procedure to complete the forms at the end of the month, prior to submitting to the local office. This makes no sense since he is both the receiver and the supplier. The form is incomplete.

Finding No. 2 - Maintenance of records and inventories

The executed DEA Forms 222 are not being maintained at the registered locations. They are being centrally located in [redacted] for safe keeping even though this is in violation of the regulations (21 CFR 1304.04).

Finding No. 4 - Year-End Reports

The Hydrocodone year-end report was reviewed. The "Disposals" quantities did not add up as waste materials are not transferred as non-salable, but as in-process materials. Waste is distinct from non-salable materials and must be reported as waste for ARCOS, Quota and the Year-End Report.

Find No. 10 - Laboratory Records

The Analytical Laboratory notebooks for material handling were not reviewed, but the research notebooks reviewed were incomplete. These co-incident activities still require the same level of documentation as other manufacturing batch records. The Adderall IR Researcher Notebook, RB-151,did not record the initial weights of materials used, the lot numbers generated for the samples created, was not clear on the total quantity of tablets used, the components used in the experiment, the serial number of the scales used, and did not describe the objective, hypothesis or summary results of the experiments reviewed.

Finding No 13 - ARCOS Reporting

ARCOS manufacturing codes are not being reported in the year-end ARCOS inventory as required. The year-end in-process inventory code "4" is currently used to include waste materials, recovered manufacturing controlled substance, scrap, QC samples, and materials awaiting disposal. The appropriate manufacturing codes should be utilized to capture and report these distinct materials.

General Recommendations

- The current Par Pharma quota application process involves soliciting controlled substance needs in June and July to prepare for August or September submissions. The DEA has requested that registrants submit procurement and import quota applications (DEA Form 250 and DEA Form 488, respectively) by April 1st of the preceding year. DEA is **required** to publish the Aggregate Production Quota ("APQ") and the Annual Assessment of Needs ("AAN") in the Federal Register on or before **May 1**. The Quota Unit cannot issue quota grants until the APQ and AAN are published. When registrants submit their requests after the April 1st deadline, they risk not having their needs incorporated in the APQ or AAN. BuzzeoPDMA recommends preparing and submitting Par Pharma quota applications by the April 1st deadline.

- A summary page should be created for each batch record to capture all DEA reportable quantities from process reconciliations. This summary should include

the theoretical, actual, waste (recovered and non-recovered, samples collected, average weights, target yield, % yields, specifications, etc. All the information necessary for the DEA Compliance group to reconcile the controlled substance usage and gather data for required DEA reporting activities is interspersed throughout the batch record. A summary page consolidating all the required data will provide efficiency and facilitate the reconciliation and accountability of controlled substances processing.

- An inventory management system similar to the Analytical Laboratory LIMS system is preferred to the ERP Inventory Management system used to track materials. The LIMS system has the capability to track bulk controlled substance, waste, QC samples, stability samples and retained samples for more complete accountability.

- Par Pharma personnel inquired about recording the invoice number on a DEA222 form being issued to a supplier. On some occasions, the supplier has rejected the order form. It is suggested that the invoice number be written on the tear-off margin around the printed order form instead of on the blank lines on the order form proper.

- Par Pharma should ensure its official records of manufacturing activity document those specific items as required per the aforementioned regulations.

QUALIFICATIONS:

1. The foregoing analysis reflects our observations and recommendations based on information and individuals made available to us by the company during the one day high level overview. An in-depth review of additional records and interviews with additional representatives would likely result in additional issues and recommendations.

2. The foregoing recommendations represent our best professional judgment based on our knowledge of the Controlled Substances Act (CSA), the implementing regulations and our experience with them. Many of the requirements of the CSA and regulations there under are subject to interpretation and are subjective. Implementation of these recommendations does not guarantee that the Drug Enforcement Administration (DEA) would not find any violations; the recommendations must be considered with this mind.

3. No analysis has been provided as to the consequences of current or prior violations of the CSA and the implementing regulations, if any, which may be noted in this report.

Raw Material Accountability - 1RR PP0244703								
1	2	3	4	5	6	7	8	9
Name & Strength of Drug	Intial Inv. as of COB 12/15/2014	Total Purchased	Total Accountable For	Closing Inv. as of 4/25/2015	Sales	Total Can Account For	Difference Over = (+) Short = (-)	Percent Difference
	+	=	Col 2 + Col 3	Count on Hand	Prescription & Log	Col 5 + Col 6	Col 7 - Col 4	Col 8 / Col 4
	grams							
DMP	347679.21	120000	467679.21	334876.534	132501	467377.534	-301.676	-0.06%
Hyd Bit	366510	0	366510	363135.391	3375	366510.391	0.391	0.00%
Clonazepam	17478.283	0	17478.283	12918.051	4410	17328.051	-150.232	-0.86%

Finished Product Accountability - 1RR								
1	2	3	4	5	6	7	8	9
Name & Strength of Drug	Intial Inv. as of OOB 12/15/2014	Total Manufactured Actual	Total Accountable For	Closing Inv. as of 4/28/2015	Sales Ship out	Total Can Account For	Difference Over = (+) Short = (-)	Percent Difference
	+	=	Col 2 + Col 3	Count on Hand		Col 5 + Col 6	Col 7 - Col 4	Col 8 / Col 4
	Units/Eaches							
DMP 15mg	0	2218400	2218400	0.00000	2218400	2,218,400	0	0.00%
Hydro 45mg	587263	0	587263	0	587263	587263	0	0.00%
Clozazepam 1mg	496100	970600	1,466,700.00	488,600	978100	1,466,700	0	0.00%

Raw Material Accountability-100B								
1	2	3	4	5	6	7	8	9
Name & Strength of Drug	Intial Inv. as of COB 12/15/2014	Total Purchased	Total Accountable For	Closing Inv. as of 4/28/2105	Amt went into MFG	Total Can Account For	Difference Over = (+) Short = (-)	Percent Difference
	+	=	Col 2 + Col 3	Count on Hand	Inv Cards	Col 5 + Col 6	Col 7 - Col 4	Col 8 / Col 4
	grams							
Methylphenidate HCl	7193.1	73000	80193.1	79591	601.9	80192.9	-0.2	0.00%

Finished Product Accountability-100B								
1	2	3	4	5	6	7	8	9
Name & Strength of Drug	Intial Inv. as of COB 12/15/2014	Total Manufactured Actual	Total Accountable For	Closing Inv. as of 4/28/2015	Sales or further mfg	Total Can Account For	Difference Over = (+) Short = (-)	Percent Difference
	+	NB/Batch Rec	Col 2 + Col 3	Count on Hand	or Dest.	Col 5 + Col 6	Col 7 - Col 4	Col 8 / Col 4
	Units/Eaches							
Morphine Active Pellets	0	6.457	6.457	0	6.457	6.457	0	0.00%

BuzzeoPDMA
Now Part of IMS Health

Via Mail and Email: Joseph.Barbarite@parpharm.com

June 4, 2015

Joseph Barbarite,
Vice President, Quality Assurance and Compliance
Par Pharmaceutical
One Ram Ridge Road
Spring Valley, New York 10977

Dear Mr. Barbarite:

Please find enclosed a summary of our recommendations pertaining to Standard Operating Procedures (SOPs) reviewed by BuzzeoPDMA Consultants during and/or after their onsite controlled substance regulatory review of the Par Pharmaceutical facilities in Spring Valley. SOPs were selected by Par Pharmaceutical staff. Comments are included for each SOP and recommendations are provided where relevant. Additional information regarding each SOP may be available in the report of …. Date… which was delivered to you on…

Please let me know if I can assist with any issues and/or items that require clarification. Also please also feel free to contact Robert Williamson, Manager, DEA Consulting.

Sincerely,

Ronald W Buzzeo

Ronald W. Buzzeo, R.Ph.
Chief Regulatory Officer

Par Pharmaceutical, Inc.

Spring Valley, New York 10977

Review of Standard Operating Procedures

The following Par Pharmaceutical (Par Pharma) SOPs were selected for Consultants to review:

- Suspicious Order Monitoring (SOM): No SO002.1

  This SOP establishes a Suspicious Order Monitoring system for all controlled substances as ordered by Par Trade Customers. "Sales Operations" is responsible for ensuring that Par Pharm is "in line" with DEA requirements. Quality Compliance is responsible for providing guidance.

  The procedure relies upon customers to provide "usage" reports. These reports are used to establish "grids" and "benchmarks." If customers order more than would be expected, a sales person would interview the customer to determine whether there is a legitimate reason for the order. This is done in writing. Ordering expectations/limitations could be changed if there is a legitimate showing.

  Due diligence is conducted on new accounts at the time they become new and quarterly. Due diligence consists of assuring that the customers have a DEA registration.

  "Suspicious Criminal Activities" are to be reported to the DEA, the FDA and the state Board of Pharmacy within three days.

  Recommendations

  Par Pharma's SOM system may be difficult to defend during a DEA SOM audit. There is no indication that the system measures or attempts to measure order size, pattern and frequency. These are the requirements in the regulations.

  BuzzeoPDMA also recommends that Par Pharma conduct additional "due diligence" on all customers. Customers should be interviewed to determine what "SOM systems" they have in place and whether Par Pharma's products are being handled in a responsible manner. Also, as a best practice, SOM decisions should be managed by regulatory officials rather than sales officials or customer service account representatives. In addition, to enhance due diligence site reviews are strongly recommended.

Any employees that receive incentives for controlled substance orders should not be involved in evaluating either accounts or orders.

As noted the entire approach to SOM should be evaluated; however, the requirement to report suspicious criminal activity rather than suspicious orders should be corrected as soon as possible, since it misses the point of the regulations. Suspicious orders should be reported as soon as they are identified.

- Inventory Control of Controlled Substances In The R&D Manufacturing Area: No. SOP-QA-0066 Draft version 0.11 and R&D Manufacturing Inventory Form: No. FRM-QA-0038

This SOP describes a process to establish a perpetual inventory of the controlled substances (CS) utilized in the R&D manufacturing suites. This form captures the information required for DEA manufacturing compliance. The current documentation process involves recording CS usage and experimental procedures in laboratory notebooks in lieu of batch records. This new procedure will replace the current laboratory notebooks as the primary CS usage and inventory tracking process.

R&D formulators or technicians will be responsible for completing an R&D Inventory Manufacturing Form (FRM-QA-0038) for each CS batch documented in an R&D notebook. The Designated Observer will be responsible for filing the form in the appropriate binder in either the DEA Cage or Vault. The DEA Specialist will be responsible for reviewing the forms and recording information for the DEA Biennial Inventory and End of Year Reconciliation activities.

This procedure outlines the proper usage of the R&D Inventory Manufacturing Form (FRM-QA-0038) and the required documentation of CS utilization in compliance with DEA R&D manufacturing coincident activities. The information on CS accountability includes: total usage, final disposition and dosage units, recoverable and non-recoverable waste, samples and retains, calculated theoretical and actual yields, and API content and reconciliation.

The R&D Inventory Manufacturing Form (FRM-QA-0038) will capture the required DEA compliance information typically included on a cGMP manufacturing batch record, but frequently overlooked in the R&D Manufacturing Laboratory Notebooks.

Recommendations

DEA continuing records regulations as promulgated in 21 CFR §1304.22 (a), delineate a list of the required elements consistent with compliant controlled substance usage documentation under a registered Manufacturer. The R&D manufacturing conducted by Par Pharma at [redacted], is

performed as a coincident activity to that Manufacturers registration and as such, is required to follow the same documentation requirements. The current primary document capture method, R&D Manufacturing Notebooks is inadequate and inconsistent in the information documented.

The R&D Manufacturing Researcher Notebook, RB-151, Adderall IR Tablets was reviewed for activity during the audit period, December 2014 - May 2015. The four split-tablet stability processes documented on pages 123-126 did not provide sufficient information to meet the DEA manufacturer records requirements: initials weights, batch numbers, list of materials & equipment, total quantity of controlled substance used, waste recaptured & discarded, labels for stability bottles, and identification or equipment number for the CII approved device the experimental bottles were to be stored, etc.

The draft SOP describes the responsibility of a Designated Observer. This position has not been approved and instituted at Par Pharma at this time. BuzzeoPDMA strongly recommends that this required, documented position be implemented in both commercial manufacturing and R&D manufacturing suites as soon as practical. The requirement of this identified position is discussed in the review of the DEA Designated Observer draft SOP-QA-0065.

- Receipt and Inventory Control of Controlled Substances: No. SOP-QA-0052 version 2.0

  This SOP describes the initial receipt, inventory, and storage of controlled substance materials into either the registered Distribution Center or the two registered Manufacturing facilities. This includes the receipt of finished packaged goods, bulk API or in-process materials. Receipts of controlled substance material into the Analytical Laboratory are described in a separate SOP.

  Purchasing Agents must notify vendors and suppliers of the appropriate receiving instruction. Warehouse or Materials Management personnel receiving the controlled substances materials will notify QA/DEA Compliance of damages or discrepancies with received goods. The DEA Specialist or designee will conduct the physical inventories at each DEA registered site.

  This SOP describes the broad processes for ordering, receiving, accessioning, storing and the inventory of controlled substance. The actual physical receiving and inventory processes beyond the weight and label verifications of the materials are not described. More detailed procedures may be described in SOP's not included in this review.

  Recommendations

  The Purchasing Agents must ensure that the appropriate documentation has been completed and the vendors or suppliers are verified DEA registrants. The nature of the receiving documentation is not described in this procedure, but an

appropriately documented DEA222 form (copy #3), a copy of the certificate of available quota (if necessary) and the Power of Attorney (should be at the same registered site) should be included. These items are required to order, receive and transact CI, CII and CIIN materials. (see 21 CFR §1303.12(f);21 CFR §1305.03;21 CFR §1305.05; and 21 CFR §1305.06 for additional information)

The Year-End Inventory is a required physical inventory that must be reported to ARCOS. The only date that is accepted in the ARCOS report for this inventory is December 31 and this inventory is to be reflective of the physical controlled substance at that registration on that day. Inventories that need to be reported and reconciled at year-end include all CII & CIIN, CIII narcotics, some psychotropic substances and GHB.

Recommendations

Page 3 - Include the Title in the CFR references (21 CFR Part 1301 & 21 CFR Part 1304.11).

Page 3 - Identify the Distribution Center as [redacted]

Page 3 - Consider a time-frame for receiving personnel to notify QA/DEA compliance of shipment irregularities.

Page 3 - Expand the described role of the DEA Specialist to include conducting year-end and special inventories as well as the biennial and initial inventories.

Page 5 - The paperwork and forms used to verify and/or document the container labels, gross weight, storage location, and signatures at steps 5, 6,7 & 8 should be identified. The executed DEA222 and the Power(s) of Attorney must be stored at the registered site.

Pages 5, 9 &10 - The allowable variance in weight of +/- 2% or >2% may be too broad for most applications. This range should be re-evaluated to take in account the original quantity of material (kg, gram, milligram, etc. and adjust the range accordingly. It is recommended that a statistical method be utilized.

Pages 6, 11, 12 & 13 - The Controlled Substance schedules should include 2N (CIIN) and 3N (CIIIN) since non-narcotic controlled substances are in inventory.

Page 6, 7 & 10 - Inventories should include the schedule of all controlled substances. Materials in schedules I & II must be maintained separately from the remaining schedules.

Page 9 - The biennial inventory is described as being conducted at the most every 2-years, but in actual practice it is performed twice a year. The Par Pharma SOP should reflect that actual practice.

Page 11 - Include GHB in the ARCOS reporting.

Page 11 -The DEA acronym is for Drug Enforcement Administration

- Distribution and Inter-Facility Movement of Controlled Substances: No.SOP-QA-0053 version 2.0

This SOP describes the processes for the transfer of controlled substances between Par facilities and to external registrants. The SOP specifically excludes transfers to and from the Analytical Laboratory. The procedure was written to be in compliance with 21 CFR §1301.

The DEA Compliance group is responsible for ensuring and enforcing compliance in the controlled substances storage areas. This includes the DEA approved vaults, cages or safes. They are also responsible for maintaining the current required controlled substances DEA and State registrations and certifications. Warehouse personnel are responsible for maintaining the approved storage conditions of the controlled substance materials until they are retrieved for transfer.

Recommendations

See CFR references for Receipt and Inventory Control of Controlled Substances: No. SOP-QA-0052 regarding DEA222 Forms, Certificate of Available Quota, and Power of Attorney. It is strongly recommended that a Global Positioning System (GPS) accompany each controlled substance distribution, whether by commercial carrier or internal company conveyance.

When the DEA Designated Observer SOP is approved, this SOP will need to be revised to incorporate that designation to required controlled substance personnel.

Page 3 - Include the Title in the CFR references, (21 CFR §1301 & 21 CFR §§1301.71-72).

Page 4 - Be consistent is terminology when referencing controlled substance schedules. Use CI and CII or Schedule I or II. Also, include the CIIN since you have non narcotic schedule II material in your inventory (ex: amphetamine).

Page 5 - The DEA 222 form needs to have the original Certificate of Available Quota (unless going to a Distribution Center) and the Power of Attorney for the registered site located at that site.

Pages 6 & 9 - For shipping to external registrants, make sure the DEA222 form and Certificate of Available Quota (if required) are completed and endorsed properly.

Pages 4-8 - Indicate that CIIN and CIIIN controlled substances are associated with the applicable registrations and through-out the SOP.

Page 7 - The DEA acronym is for Drug Enforcement Administration

- DEA Designated Observer, No.: SOP-QA-0065, DRAFT version 0.220

This draft SOP describes in detail the Par responsibilities and duties of the DEA Designated Observer or Authorized Observer for all Manufacturing activities. Employees, Supervisors and Managers are responsible for ensuring compliance with the Designated Observer role. Once assigned the designation, the individual(s) assume a myriad of tasks well beyond the intended scope of the regulation.

The draft Designated Observer SOP extends the responsibilities substantially and may require a third person not associated with the manufacturing activity to be present to fulfill the roll. This is in excess of the DEA's intent, but may be entirely appropriate for Par Pharma's business goals and security concerns.

Recommendations

DEA regulations are very specific in their requirements: this person(s) must be identified in writing, they are responsible for defined "Limited Access" areas, and while permitted to engage in manufacturing activities, they must provide continuous surveillance to detect & detain unauthorized persons.

The Designated Observer's main objective is to ensure the limited access areas where controlled substances are present remain free from unauthorized personnel. If a non-authorized individual is present for legitimate business reasons, repairs or maintenance, etc., the Designated or Authorized Observer is to monitor their presence. This is the extent of the requirement in the regulations, 21 CFR § 1301.73(b).

Manufacturing observers should be designated in writing as a posted list in the manufacturing area and as part of the manufacturing record itself. The observers may be engaged in the manufacturing process itself and need not be independent of the activity being performed as long as they understand their primary and most important role. The list should be retrievable for the manufacturing activity.

A second list of individuals authorized to observe non-routine, such as non-approved employees, non-employees, maintenance personnel, etc., access to the controlled substance safes and storage areas should be created and posted at each location.

Also, all employees engaged in controlled substance processing or in proximity of controlled substance processing are required to be vigilant to unauthorized persons or activities. This is true whether or not an employee has been identified

as the Designated Observer. Not having employees identified specifically as Designated Observers does not alleviant the requirement to monitor for unauthorized persons or activities (see 21 CFR §1301.91 for additional information regarding employee responsibilities to report diversion)

Page 3 - Include the Title in the CFR references, (21 CFR §§1301.73 & 1301.91)

Page 5 - Reconciliation issues must be reported for further investigation. It is recommended that a timeframe from discovery to notification be established.

Page 5 - While the Designated Observer is required to be present and identified in writing during manufacturing activities, it should be clarified that they may also be engaged in the manufacturing activity. See above for primary function.

Page 8 - The Trash Inspection tasks could be part of the suite set-up prior to of following a process.

Page 10 - the definition for Designated Observer is not in-line with DEA regulations. Technically, the role is to prevent unauthorized access to defined limited access controlled substance manufacturing or storage areas.

QUALIFICATIONS:

1. The foregoing analysis reflects our observations and recommendations based on information and individuals made available to us by the company during the one day high level overview. An in-depth review of additional records and interviews with additional representatives would likely result in additional issues and recommendations.

2. The foregoing recommendations represent our best professional judgment based on our knowledge of the Controlled Substances Act (CSA), the implementing regulations and our experience with them. Many of the requirements of the CSA and regulations there under are subject to interpretation and are subjective. Implementation of these recommendations does not guarantee that the Drug Enforcement Administration (DEA) would not find any violations; the recommendations must be considered with this mind.

3. No analysis has been provided as to the consequences of current or prior violations of the CSA and the implementing regulations, if any, which may be noted in this report.